IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SALIX PHARMACEUTICALS, INC. and
DR. FALK PHARMA GmbH,

Plaintiffs,

v.

G&W LABORATORIES, INC.

Defendant.

C.A. No. 14-213-GMS
(CONSOLIDATED)

Redacted Version of D.I. 168

JOINT STATUS REPORT

Pursuant to the Court's Order issued at the end of the telephonic Status Teleconference held on May 26, 2016, Plaintiffs Salix Pharmaceuticals, Inc. and Dr. Falk Pharma GmbH (collectively "Plaintiffs") and Defendant G&W Laboratories, Inc. ("G&W" or "Defendant") (collectively, "the Parties"), by and through their undersigned counsel, submit this Joint Status Report. Counsel for the Parties have met and conferred in an effort to come to an agreement regarding a discovery and trial schedule for the Parties' remaining countervailing infringement and invalidity claims.

1. Remaining Issues to be Tried

a. Joint Summary of Trial Proceedings to Date

This case involves four asserted patents: (1) U.S. Patent No. 6,551,620 (the "'620 patent"); (2) U.S. Patent No. 8,447,886 (the "'886 patent"); (3) U.S. Patent No. 8,496,965 (the "'965 patent"); and (4) U.S. Patent No. 8,865,688 (the "'688 patent"). The claims and defenses pertaining to the '620 patent, the '886 patent and the '965 patent (collectively known as the "Otterbeck patents"), were tried in November 2015. While limited testimony regarding the '688 patent was presented at trial, this patent could not be fully tried at that time because one of Plaintiffs' expert witnesses pertaining to the '688 patent was out of the country.

b. Plaintiffs' Position on Remaining Issues to be Tried

Plaintiffs' submit that there is no need for the Court to issue an opinion on the Otterbeck patents in view of G&W's anticipated launch date [redacted] (*see* D.I. 159 at 6:19-7:1)—[redacted]. However, should the Court decide to issue an opinion on the Otterbeck patents, Plaintiffs believe the opinion should be rendered on the product that is likely to be sold. (*See, e.g.,* D.I. 159 at 11:19-12:1 & 12:7-12:17.) [redacted]. (*See, e.g.*, D.I. 159 at 14:18-15:1.)

Plaintiffs' position is that additional expert testing, reports and testimony relating to some claims of the Otterbeck patents may be needed following discovery in view of [redacted].

Assuming that only infringement and invalidity claims relating to the '688 patent remain at issue,[1] Plaintiff estimates that one to two days will be sufficient to complete trial of the remaining claims and defenses regarding the '688 patent. If expert testing, reports, and depositions are required on issues related to claims of the Otterbeck patents [redacted] Plaintiffs estimate that a total of 3 to 4 days could be required for trial.

[1] In response to Defendant's claim that neither the parties nor the Court indicated that any issues remained to be tried on the Otterbeck patents at the adjournment of the November 2015 trial, Plaintiffs submit that they were not aware [redacted].

c. Defendant's Position on Remaining Issues to be Tried

It is Defendant's position that all claims and defenses related to the Otterbeck patents were fully tried in November 2015, [redacted]. The only issues that remain to be litigated are those pertaining to the '688 patent, which is a method of treatment patent. At the adjournment of trial in November 2015, neither the parties nor the Court indicated that any issues remained to be tried on the Otterbeck patents. [redacted].

Plaintiff's arguments about the continued justiciability of the Otterbeck patents are at direct odds with statements Plaintiffs' counsel made to the Court at the Status Conference on May 26, 2016. [redacted], Plaintiffs' counsel stated several times that there was no need for the Court to issue an opinion on these patents. (*See* D.I. 159 at 4:2-3; 6:19-7:1; 11:2-8.) At the time, Plaintiffs [redacted] did not state that any claims related to the Otterbeck patents would need to be re-litigated [redacted]. Plaintiffs' counsel effectively acknowledged the Otterbeck patents were fully tried by identifying only the '688 patent as "the patent which we still have not completed trial on." (D.I. 159 at 5:18-19.)

Moreover, when the parties met and conferred in advance of this Joint Status Report, the parties only discussed the [redacted] data that Plaintiffs believe their expert needs in order to supplement her opinion with respect to a limitation recited in the '688 patent. Defendant's counsel confirmed the substance of the Parties' meet and confer discussions on these points, and Plaintiffs posed no objections and offered no corrections. (*See* December 27, 2016 e-mail attached hereto as Exhibit A.)

Plaintiffs' argument that the Otterbeck patents might somehow come back into play [redacted] lacks merit. Plaintiffs again seek to

manufacture another reason to delay trial without justification. As the Court may recall, Plaintiffs repeatedly tried to delay trial over a year ago because one of their experts elected to schedule a trip to Africa right in the middle of trial. (*See, e.g.*, D.I. 141.) Indeed, even the Court acknowledged at the May 26, 2016 status conference that "Plaintiffs want to postpone trial again." (D.I. 159 at 2;16.) Plaintiffs' present attempt to indefinitely postpone trial on the '688 patent based on the fully litigated Otterbeck formulation patents that will expire in April 2018 should be rejected.

2. Joint Statement Regarding Status of G&W's ANDA

[redacted]. (*See* Exhibit C attached hereto.) [redacted] (*See* Exhibit D attached hereto.)

3. The Parties' Positions on Relevant Product Testing

a. Plaintiffs' Position

During the telephonic Status Conference on May 26, 2016, Plaintiffs' counsel informed the Court [redacted] (*See*

D.I. 159 at 3:16-21; 4:22-23; 5:13-21; 13:10-18.) Plaintiffs submit that these are the test results Plaintiffs need in view of what Plaintiffs *currently know* [redacted] in order to complete trial on the '688 patent. [redacted] (*see* Ex. B attached hereto), and Plaintiffs need additional discovery to assess G&W's proposed product. If, after receiving [redacted], only a re-analysis of the release limitation in the '688 patent claims is required, the Parties would need some limited time to conduct discovery on these issues [redacted]. Such discovery would include a Rule 30(b)(6) deposition regarding [redacted], and potential supplemental expert reports on infringement from Plaintiffs regarding [redacted] and rebuttal expert reports from Defendant followed by depositions of the Parties' experts. (*See id*. at 13:10-18; 21:8:-10; 21:22-2.)[2]

b. <u>Defendant's Position</u>

Plaintiffs' statements to the Court on May 26, 2016 are very different from what Plaintiffs are now stating. While Plaintiffs now claim that [redacted] might open a Pandora's box of necessary discovery, the transcript from May 26th states that the only data Plaintiffs need to prove their infringement case on the '688 patent is the data regarding [redacted]. During that May 26th Status Conference, Plaintiffs' counsel repeatedly focused on these two particular tests and studies:

- [redacted] (D.I. at 5:13-21.)

[2] While Plaintiffs hope that, after receiving [redacted], all that is at issue [redacted] is infringement of the release limitation of the asserted '688 patent claims, Plaintiffs will not know this until they have this discovery.

- [redacted]

  (*Id*. at 5:25-6:4.)
- [redacted] (*Id*. at 13:14-16.)
- [redacted] (*Id*. at 14:24-15:1.)

In reliance upon Plaintiffs' statements to the Court on May 26th, G & W has diligently attempted to gather information regarding the timing and data for these studies; G & W then promptly communicated this information to Plaintiffs with the hope that the parties can agree on a finite amount of supplemental discovery to be completed in a short period of time. G&W expects to have [redacted], and expects to have [redacted] G&W's counsel communicated these testing completion dates to plaintiffs' counsel on Tuesday, December 27, 2016.

Plaintiffs' new contention that [redacted] might open a floodgate for additional discovery is speculative and unsupported by any facts or plausible argument.

4. Proposed Trial and Limited Additional Discovery Schedule

a. Plaintiffs' Position

Plaintiffs are not fundamentally opposed to Defendant's proposal of a trial in late Fall 2017 if: (1) G&W completes and produces [redacted] by late July 2017; and (2) there are no additional issues aside from infringement of the release limitation of the asserted '688 patent claims raised by discovery of [redacted].[3] However, given the uncertainty of

[3] Plaintiffs disagree with Defendant's schedule set forth below, not only as premature and potentially short on trial days depending on what limited discovery reveals, but also because, Defendant has assumed there will be one specifically named expert (Dr. Golden) for Plaintiffs, and has left little to no time for any exchange of a pretrial order if necessary. Defendant has

the two issues listed above, including when and what will be ascertained from limited discovery, Plaintiffs believe it is premature to set a trial date at this time. Instead, Plaintiffs propose that the Parties meet and confer and submit a Joint Status Report after July 2017 [redacted] with a reasonable schedule for limited discovery leading to a trial.

Nor are Plaintiffs trying to delay or postpone trial.[4] Plaintiffs are simply trying to ensure that the Court's opinion addresses the product on which G&W seeks approval and that is likely to be sold in view of [redacted] and the potential impact on the data on which Plaintiffs' rely.

b. Defendant's Position

Defendant respectfully requests that the Court schedule trial in the Fall of 2017 [redacted]. Plaintiffs' position that no trial date should be set at this point is contradictory to Plaintiffs' statements to G&W on December 27, 2016. Plaintiffs cannot in good faith fundamentally agree to a Fall 2017 trial date and simultaneously request the Court not set a trial date at this time and instead require the Parties to submit another Joint Status Report in July 2017 [redacted]. It is well understood that in light of the Court's very congested docket, the Court will not have available a Fall 2017 trial date when the Parties submit the July 2017 Joint Status Report advocated by Plaintiffs.

As such, and as the Court's calendar permits, Defendant proposes the following trial and limited additional discovery schedule. [5]

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agreed to accommodate Plaintiffs' request for a 30(b)(6) deposition and a rebuttal expert witness deposition, which will be worked into any schedule.

[4] Further, Plaintiffs never requested a delay in the November 2015 trial, but merely certain expert testimony on the '688 patent (see D.I. 114).

[5] In response to Plaintiffs' comments in footnote 3 above, Defendant invites Plaintiffs to propose dates for a Rule 30(b)(6) deposition and a rebuttal expert witness deposition. Regarding Pamela Golden, she is the only expert witness Plaintiffs identified in the Parties' meet and confer communications as having a need to analyze the dissolution and bioequivalence data and issue a

Event	Proposed Date
Supplemental Expert Report from Plaintiffs' Expert, Pamela Golden	August 18, 2017
Rebuttal to Plaintiffs' Supplemental Expert Report from G&W's Expert, Richard Brundage	September 8, 2017
Deposition of Pamela Golden	Not later than September 29, 2017
Trial	Two consecutive days between October 23 and November 3, 2017

G&W submits that its proposed schedule is both feasible and realistic. Moreover, the risk that Plaintiffs will not have sufficient time to complete the discovery they believe G&W's test data and studies will prompt in advance of a Fall 2017 trial date lies exclusively with G&W. In other words, in the highly unlikely event that a Fall 2017 trial date set now will need to be continued as a result of the [redacted], it is G&W that would suffer from a further trial continuance, not Plaintiffs. Concomitantly, a delay in setting a Fall 2017 trial date now pending another Joint Status Report from the Parties some seven or eight months down the line benefits only the Plaintiffs, and prejudices G&W by forcing G&W to wait an undetermined additional amount of time to complete trial on the '688 patent.

supplemental report concerning the same. Indeed, Dr. Golden is the only expert witness on the Plaintiffs' side who offered product release opinions at the November 2015 trial.

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